K090953

# 510(k) Summary
# for
# TOTAL KNEE SURGETICS Navigation System with iBlock

## 1. Submitter Name and Address:

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France

JAN 21 2010

Contact Name: Sébastien Burtin
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Date Prepared: March 13th 2009

## 2. Device Name:

Proprietary Name: TOTAL KNEE SURGETICS Navigation System with iBlock
Common/Usual Name: Image guided surgical navigation system
Classification Name: Stereotaxic instrument

## 3. Predicate Device:

PRAXIM – TOTAL KNEE SURGETICS Navigation System with Praxiteles (K081232)

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## 4. Intended Use:

The TOTAL KNEE SURGETICS NAVIGATION SYSTEM WITH IBLOCK is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning the endoprostheses with the anatomical structures.

It is specifically indicated for:

- Total Knee Arthroplasty

## 5. Device Description:

As the equivalent TOTAL KNEE SURGETICS NAVIGATION SYSTEM WITH PRAXITELES, the TOTAL KNEE SURGETICS NAVIGATION SYSTEM WITH IBLOCK consists of the following major components and subsystems:

- The Station (Surgetics or NanoStation), consisting of a mobile computer system and an optical localizer
- Ancillary instruments, a specific motorized cutting block and reflective markers used for reference and registration
- TOTAL KNEE SURGETICS software application with iBlock option

The main modification to the predicate device K081232 concerns the modification of the motorized cutting block PRAXITELES®.

## 6. Technological Characteristics and Substantial Equivalence

The underlying technology of the TOTAL KNEE SURGETICS Navigation System with iBlock is the same as for the predicate device K081232. The system is based on the same operating principle and control mechanism to provide the user with the same kind of information and guidance for the same surgery. The main changes with respect to the predicate device concern the modification of the motorized cutting block Praxiteles. The iBlock® is an improved version of the Praxiteles motorized cutting block and is also controlled by the navigation system. Once the cutting block has been positioned to the desired cut, the surgeon can proceed to the cut as it is done in the conventional way using a traditional saw.

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## 7. Performance Testing

The TOTAL KNEE SURGETICS Navigation System with iBlock was tested in a non clinical setting (bench testing, specimen) to assess that no new safety and efficiency issues were raised with this device. Analyses show that the accuracy and performance of the system are adequate for its intended use and not reduced in comparison to the predicate device.

In conclusion the modified device TOTAL KNEE SURGETICS Navigation System with iBlock is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room W-O66-060
Silver Spring, MD 20993-0002

Praxim S.A.
% Mr. Sébastien Burtin
Regulatory Affairs and Quality
Assurance Director
Le Grand Sablon
4, Avenue De L'Obiou
38700 La Tronche, France

JAN 21 2010

Re: K090953
Trade/Device Name: TOTAL KNEE SURGETICS Navigation System with iBlock
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 16, 2009
Received: December 23, 2009

Dear Mr. Burtin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PRAXIM

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# STATEMENT OF INDICATIONS FOR USE

# TOTAL KNEE SURGETICS Navigation System with iBlock

510(k) Number (if known): K090953

Device Name: TOTAL KNEE SURGETICS Navigation System with iBlock

The TOTAL KNEE SURGETICS Navigation System with iBlock is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning the endoprostheses with the anatomical structures.

It is specifically indicated for :

* Total Knee Arthroplasty

Prescription Use ___X___ AND / OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K090953